interferon which is in excess of a dose of the same interferon which induces a pathological response when parenterally administered. Preferably, the dose is greater than 20×10^6 IU for a 70 kg human. The interferon is administered to a mammal which has a viral infection and is used for treating the infection, as opposed to mere prophylaxis.

Claims 7 and 21-35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hayden. The examiner states that Hayden teaches the application of interferon for treating rhinovirus infection and other respiratory viral infections using a single treatment by intranasal drops. The examiner states that nose drops will contact the oromucosa and a person of ordinary skill in the art would be motivated to treat viral infection with the prior art anti-viral interferon in the absence of a side-by-side comparison. This rejection is respectfully traversed.

Hayden does not disclose the treatment of a viral infection. While the examiner refers to page 550, column 1, it is believed that this sentence is taken out of context. In context the entire last paragraph of Hayden reads:

> A practical application for the use of IFN-α2 would be its <u>prophylactic</u> use by members of a family in which a member had developed a new cold, since intrafamilia spread is an important route of RV transmission [23]. Alternative target groups who are at increased risk for respiratory complications of rhinovirus infection include asthmatics

> [23, 24] and those with chronic lung disease [25]. The present study provides preliminary evidence to indicate that intranasal IFN-α2 could be safely used in asthmatic patients. Field trials of intranasal IFN-α2 in natural rhinovirus and other respiratory viral infections are warranted. [emphasis added]

Thus, in context it is apparent to one of ordinary skill in the art that the field trials being referred to are field trials of the prophylactic use of interferon against natural rhinovirus and other respiratory viral infections. This is consistent with the first and last sentences of the abstract, which read:

> In two placebo-controlled, double-blind studies, the prophylactic efficacy of recombinant DNA-produced interferon α2 (IFN-α2) against induced rhinovirus (RV) type 39 infection in susceptible volunteers was assessed. ... The results suggest that intranasal IFN-α2 may prove to be a safe and effective method of preventing rhinovirus infection and illness. [emphasis added]

Thus, the only suggestion in Hayden relates to prevention. Nowhere in Hayden is there any suggestion that interferon, particularly in the doses specified, would be useful for treatment of a viral infection. Indeed, Hayden reports in the first paragraph that the prior art has found that intranasal spraying of HuIFN-α in high dosages was not effective against infection following viral challenge, noting where it states:

> Scott et al [3] have reported that repetitive intranasal spraying of highly purified HuIFN-α in high dosages (90×10^6 IU

over four days) had significant protective effect against illness but not against infection following challenge with an experimental strain of RV type 9.

Claim 7 has now been amended to make even more clear that the present invention is related to treatment by making further explicit that the interferon is administered to mammals having a viral infection. This is not disclosed by Hayden nor is it made obvious by Hayden. As no *prima facie* case of obviousness is established by Hayden, for the reasons given above, there is no need to provide side-by-side comparisons. Accordingly, reconsideration and withdrawal of this rejection are respectfully urged.

It is submitted that all of the claims now present in the case clearly define over the references of record. Reconsideration and allowance are, therefore, earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By _____
Roger L. Browdy
Registration No. 25,618

RLB:rd
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
F:\,P\phaq\Tovey1A\Pto\AmendmentB.doc